Division of Dockets Management
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Re: Docket Nos. 1996P-0418, 1997P-0197, 1998P-0203 and 2000N-0504

Dear Sir or Madam:

I am submitting this comment on the FDA's proposed rule on *Salmonella* Enteritidis in shell eggs. I am the chief operating officer of an large egg producing company operating in Maryland, New Jersey, Delaware and South Carolina. I believe my background as a lab technician, ingredient producer/purchaser/supervisor at a food processing company, operations manager, and now as a corporate officer of an egg producing company has given me a unique perspective into this issue of Se in shell eggs and the impact of the proposed requirements. I would be remiss if I failed to mention that also as a consumer I have the privilege to prepare shell eggs for my family at least once a week.

The need for an egg producer to have some type of formal Egg Safety/Testing program is irrebuttable. The requirements as outlined in the proposed rule however overstep the bounds of both practicality and science. The major concerns (for the sake of brevity) that I have are as follows:

1. An umbrella, FDA monitored program would be too subjective and vague as to evaluating the Prevention Measures, with the only exception being the clearly defined standards of the NPIP. The other measures do not provide a clear standard or limit. An objective measure of the outcome (a positive manure sample) should be the trigger to re-evaluate the producers' current program. All producers should have an approved state or company developed monitoring program as their standard. The frequency of monitoring performed in the layer house as defined in the proposed rule is not overly burdensome, in my opinion, but the narrow range of sampling dates are too restrictive. NPIP and Compliance with a monitoring protocol and related testing are the only measurable enforcement areas. . **Recommendation: Only require NPIP and Monitoring/Testing as a preventive measure and only mandate implementing specific Pest Control, Biosecurity, and Cleaning and Disinfection Procedures upon an environmentally positive manure swab.**

2. A site or farm specific set of Best Management Practices should contemplate a vaccination program based upon the outcome or results of the monitoring. Consideration of if, when, and what type of Se vaccinations should be made and encouraged as deemed appropriate by a professional. Neither too much or too little of a vaccination program would be in the best public interest if the outcome did not warrant the appropriate vaccination response. FDA efforts to "penalize" a positive environmental swab would most likely prompt producers to over vaccinate versus evaluate the management

practices. In other words, treating the symptom with a vaccination may not result in a remedy of the cause. Long term success will be found only in educating the farmers to change and improve their production practices. This will not happen if "coerced" by the FDA through subjective regulations specific to Biosecurity, Pest Control, and Cleaning. Our company has emphasized the "PULL" of our Customers requiring a HAACP type of program versus the management's (or government's) "PUSH" of forcing a program. If the swab results warrant management review or if mandated by a customer, then a formally designed program must be in effect. This concept has worked quite well for us since its inception in 1994 with McDonald's. **Recommendation: Add as a preventive measure the discretionary but specific evaluation and use of Vaccines as a part of a total program control Salmonella along specific Pest Control, Biosecurity, and Cleaning and Disinfection Procedures upon an environmentally positive manure swab.**

3. Having worked in a Microbiological lab that tested for Salmonella, I know the impact of space limitations and procedural challenges that occur when there is a significant increase in the number of samples. Media, incubation and sample storage space, all are affected for an extended period of time. Again, the goal should be quality and integrity of the management/testing program not compromising validity or consistency of the results from a massive influx of manure samples. **Recommendation**: **Consideration should be given towards the approved lab community's ability to handle this increase in testing.** I am aware that the USDA/FSIS Salmonella proficiency testing program was suspended for an extended period due to lack of resources. We continued to sample and test as per our company program requirements even though the quarterly analysis and validation of USDA/FSIS recognized labs was suspended indefinitely.

4. From my perspective, the costs associated with regulating these rules are disproportionate to the problem. The additional costs to the producers must be absorbed through improving production practices and other efficiencies. As stated earlier, the need to monitor and understand the risk is irrebuttable. The costs however, should reflect a response to a legitimate need. To require wet cleaning of equipment which will not only rapidly deteriorate equipment but also will not effectively mitigate the problem at hand will result in unwarranted higher operating costs. Positive results must be validated and treated in a more responsible and economically prudent manner. Accelerating refrigeration times and temperatures in a negative environment and negative egg will only waste huge sums of money in refrigeration and related utilities expense. **Recommendation: Evaluate the benefits of stepping down the temperatures (from 45 to 60 or 55 F.) over a longer period of time (from 36 to 72 hrs.) especially where there is no history of salmonella problems existing. Change the wet cleaning language to dry cleaning only for environmental positives.** These changes represent the opportunity to minimize the ever increasing costs of moving towards an effective food safety program.

Relative terms such “clean”, “remove debris”, “control” , “prevent”, “ensure”, etc., should be excluded from regulatory evaluations and be left to the producers’ discretion and responsibility. These are the management production practices which should *result* in a clear measurable outcome--a positive or negative egg, which could and should be regulated.

In conclusion, I repeat that our farms have seen the need for a comprehensive food safety program and recognize the risk of *Salmonella* enteritidis. Our concern is not only for the industry but the consumers, our customers. We also recognize that we as farmers and egg processors can do everything perfectly but lose control of the safety of the product once it is delivered. Consumer education and food worker training will have to be an integral aspect of an effective overall program and must be addressed. Our desire is to see regulatory changes that are specific measures which will provide practical solutions and be readily acceptable by small and large farmer alike.

Sincerely,

Gregg Clanton
ISE America, Inc.